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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,829	03/23/2005	Andrew Lennard Lewis	Q86429	3735

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EXAMINER	
DICKINSON, PAUL W	
ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,829	LEWIS ET AL.	
	Examiner	Art Unit	
	PAUL DICKINSON	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *51-53 and 70-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51-53 and 70-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 8/28/2008, have been fully considered but they are not deemed to be fully persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Response to Arguments

Although Applicant has overcome by amendment the rejection of Claim 51 under 35 U.S.C. 102(a) and (e) as being anticipated by US 6416740 ('740), this document is used in a new grounds of rejection below. Accordingly, the Examiner would like to respond to Applicant's arguments.

Applicant argues that '740 is directed to gaseous precursor filled vesicles (i.e. microspheres) wherein the vesicles only encapsulate gas or gaseous precursors, whereas the instantly claimed polymer matrix extends throughout the particle and is thus not limited to such a configuration.

Applicant's arguments have been fully considered but are not found persuasive. In response to Applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the polymer matrix must extend throughout the particle) are not recited in the rejected claim. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26

USPQ2d 1057 (Fed. Cir. 1993). '740 clearly teaches incorporation of polymers (a polymer matrix) into the particles (see col 4, lines 32-38; col 15, lines 43 to col 16, line 58; col 19, line 41 to col 20, line 43).

Claim Rejections - 35 USC § 103

The rejection of Claims 51 and 70-78 under 35 U.S.C. 103(a) as being unpatentable over JP 11-322948 (JP '948) is maintained.

Applicant argues that it would not have been obvious to optimize the particle size disclosed by JP '948, through routine experimentation, to find the instantly claimed particles size of 150 microns to 3000 microns, as JP '948 discloses the range of 1 nm to 100 microns, which does not overlap with the presently claimed range.

Applicant's arguments have been fully considered but are not found persuasive. The Examiner agrees that JP '948 teaches particle sizes ranging from 1 nm to 100 microns. There is no teaching in JP '948, however, that suggests particle sizes over 100 microns could not be used in carrying out the invention. Although the range disclosed by JP '948 and the instant range do not overlap, they are close to each other, and the maximum of 100 microns disclosed by JP '948 and the minimum of 150 microns disclosed in the instant claims differ by 50 percent, and the "real world" particle population made would reasonably be expected to differ even less when error and variation in particle size is accounted for. It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to explore larger particle diameters than those taught by JP '948, to optimize the rate of drug release from the

particles, especially in the case of water soluble therapeutic agents. In this way, one would reasonably arrive at the instantly claimed range of 150 to 3000 microns. See MPEP § 2144.05, II.

The rejection of Claims 52-53 under 35 U.S.C. 103(a) as being unpatentable over JP 11-322948 (JP '948) in view of WO 010303666 (WO '666) in further view of Ishihara et al (Polymer Preprints, 2001) is maintained.

Applicant argues, in addition to the above regarding JP '948, that the polymer composition of JP '948 and WO '666 are substantially different. WO '666 administers the composition as a liquid precursor which precipitates after administration to form occlusive aggregates of polymer to form a mass. Although JP '948 describes particulate compositions, JP '948 does not describe the formation of agglomerates *in situ* after administration. Ishihara et al relates to compositions used to coat a variety of materials, including nanoparticles having a diameter around 200 nm. Ishihara et al does not disclose embolic compositions, nor particles having the dimensions recited in Instant Claim 51.

Applicant's arguments have been fully considered but are not found persuasive. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in

the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In the present case, the Examiner relied on the teaching of Ishihara et al that acrylate copolymers of 2-methacryloyloxyethyl phosphorylcholine have excellent biocompatible and antithrombogenic properties, and not on the use of this material, *per se*, disclosed in the remainder of the reference. Although JP '948 does not describe the formation of agglomerates *in situ* after administration, this characteristic is inferred by WO '666 (WO '666, Claims 1 and 17). It would be obvious to administer the composition disclosed by JP '948 in an appropriate solvent, according to the method taught by WO '666, to serve as an embolization material (see WO '666, page 9, line 10 to page 10, line 24; Claim 1). WO '666 teaches the effectiveness of phosphorylcholine polymer compositions to serve in this capacity (i.e. to precipitate out of the solution/suspension to form an embolus), and the polymers disclosed by JP '948, namely acrylate copolymers of 2-methacryloyloxyethyl phosphorylcholine, are phosphorylcholine polymers with excellent biocompatible and antithrombogenic properties. Thus, it would be reasonable to try to incorporate the phosphorylcholine polymer composition disclosed JP '948 into the invention of WO '666, with a reasonable expectation of success, to afford an embolization material that provides excellent biocompatible and antithrombogenic properties.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6416740 ('740). '740 discloses the administration of a composition to an animal, wherein the composition comprises particles of a polymer matrix into which is absorbed aqueous liquid, the particles having diameters in the range of 100 microns to 1 mm

(1000 microns), wherein the surface of the particles express zwitterionic lipids (see abstract; col 4, lines 22-31; col 6, lines 5-8; col 20, line 46; Figures 1-3; Claim 1). The particles may be fully imbibed with water (see col 5, line 67). '740 fails to disclose particle diameters in the range of 150 microns to 3000 microns.

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to optimize the particle diameter of '740, through routine experimentation, to find the instantly claimed range of 150 microns to 3000 microns, as the range disclosed by '740 of 100 microns to 1000 microns overlaps with the instantly claimed range. See MPEP § 2144.05, II.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

November 18, 2008